AUG 2 7 2001

K012754

Section 1 – Information Required by the Safe Medical Devices Act of 1990

1.1 510(k) Summary

Submitter: Animas Corporation, 590 E. Lancaster Avenue, Frazer, PA 19355

Contact: Michael J. Andrews, Ph.D., Director, Regulatory Affairs,
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Name of Device: Animas EZ Set Infusion Set

Predicate Device: MiniMed Paradigm Silhouette Infusion Set, Maersk Medical Comfort Infusion Set, Disetronic Tender Infusion Set

Description of the New Device: The Animas EZ Set Infusion Set is an infusion adminstration set with the proximal end connecting to a medicine reservoir syringe within an infusion pump and the distal end inserted in the subcutaneous itssue of a user.

The device consists of two components, an infusion site assembly and a tubing connector assembly. The infusion site assembly consists of a cannula housing with a disposable insertion hub assembly. The main body of the cannula housing has a thin self-adhesive pad for attachment to the skin. A soft flexible 22 gauge cannula extends below the flat bottom of the housing to penetrate the skin at a slight angle. A detachable insertion needle assembly is intitially connected to the cannula housing assembly to insert the soft flexible cannula subcutaneously. It is then removed and replaced by the needle hub assembly to deliver medication. An elastomeric septum seals the entrance to the cannula when the needle hub assembly is removed.

The tubing connector assembly consists of a length of flexible plastic tubing made from polyvinyl chloride with a co-extruded polyethylene liner. The tubing is attached to a female Luer Lock connector at one end and a short needle mounted in the main body of the needle hub at the opposite end. The main body provides a means to align and attach the needle hub to the cannula housing assembly by means of a quick release connector. When the cannula housing and the needle hub are connected, the needle penetrates the septum allowing medication to flow from the pump through the flexible tubing, the needle, and the cannula into the patient's body. The needle hub assembly may be easily released from the cannula housing by squeezing the resilient side members deflecting the retaining band above a bump on the cannula housing. This allows the needle housing to slide freely off the cannula housing. The quick release

connector allows the user to temporarily disconnect the tubing at the insertion site for activities such as dressing or bathing.

In addition to complete administration sets, infusion site sets without the tubing and quick release connector will also be available.

Intended Use of the New Device: The Animas EZ Set Infusion Set is intended intended to provide subcutaneous infusion of medicine, including insulin, from an external infusion pump.

This device is intended for home use and is a prescription device.

Comparision of the Technological Features of the New Device and the Predicate Device: The new device and the predicate devices are substantially similar in in terms of components, locking mechanisms, coextruded tubing, Luer connections to the medicine reservoir, the indwelling cannula, and the introducer needle. The devices are constructed from substantially similar materials. The devices are intended to deliver insulin and other medicines subcutaneously from an external infusion pump to the user.

The differences between the new device and the predicate devices do not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Animas Corporation
C/O Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K012754
Trade/Device Name: EZ Set Infusion Set
Regulation Number: 21 CFR 880.5440
Regulatory Class: II
Product Code: FPA
Dated: May 30, 2001
Received: August 16, 2001

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

his response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number: K012754

Device Name: Animas EZ Set Infusion Set

Indications for Use: The Animas EZ Set Infusion set is intended to provide subcutaneous infusion of medicine, including insulin, from an external infusion pump.

This device is intended for home use and is a prescription device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012754